

REMARKS

In paragraph 2 of the Office Action, claims 1, 3, 5-16 and 21-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sparks et al. (Sparks).

Reconsideration is requested.

The Sparks patent discloses a controlled release pharmaceutical formulation which is based on microparticles. The claims before the Examiner point out an effervescent pharmaceutical composition for administering particular drugs in microcapsules having a D50% between 100nm and 900nm in which the drug is entrapped in a biodegradable polymer.

At col. 7, lines 39-55 Sparks does not teach effervescent microparticles. What is taught is the separate use of acid and basic materials for achieving a desired effect with certain drugs. The combined use of acid and base to achieve an effervescent composition is not taught because that would require a mention of a separating material to prevent spontaneous decomposition. The mention of effervescent tablets at col. 7, line 52 does not suggest that the effervescent materials should or could be incorporated into the microparticles. These tablets are mentioned in the same context as other tablet dosage forms which, in context, make it apparent that Sparks was merely adding the microparticles to a compressible granulation and had no concept of adding the effervescent ingredients to the microparticles.

Sparks discloses drug release data for particles having a size range of 90 to 125 μ m in Examples 1-10. The data that Sparks reported for drug release in simulated intestinal fluid, from microparticles having a drug load of about 9%w/w was 70-100% after 6 hours and after 8 hours was 78-100%. The data reported for the applicants microcapsules at drug loads of 20%w/w and 30%w/w at a pH of 7.4, which approximates simulated intestinal fluid, is about 20% as shown at Figs. 5 and 6 of the present specification. This data shows that the microcapsules having a D50% of 100-900nm have a much slower release profile than do the microparticles of Sparks.

At col. 9, lines 64-69, Sparks explicitly distinguishes his microparticles from microcapsules:

The microparticles according to the invention are to be

distinguished from microcapsules in that in the latter the active ingredient is encapsulated by a polymer coating, whereas in the former the active ingredient is uniformly dispersed throughout the polymer material as described above....

The direct quotation, from the Sparks patent, is persuasive evidence that the claimed microcapsules are not made obvious by the cited reference. For these reasons, it is requested that this ground of rejection be withdrawn.

An early and favorable action is earnestly solicited.

A Power of Attorney from the Assignee to the undersigned is attached to this Amendment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. V. Costigan', is written over the printed name.

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